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Mark J. Murphy				
Cook, Alex, McFarron, Manzo,				
Cummings & Mehler, Ltd.				
200 West Adams St., Ste. 2850				
Chicago, IL 60606				
			EXAMINER	
			SCHELL, LAURA C	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/694,032

Applicant(s)

HUGHETT ET AL.

Examiner

Laura C. Schell

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10 and 20-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10 and 20-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/16/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Liprie (US Patent No. 6,635,008) in view of Waksman et al. (US Patent No. 7,160,238) and further in view of Liprie (US Patent No. 5,800,333) and further in view of Meloul et al. (US Patent No. 6,013,020). Liprie'008 discloses the device substantially as claimed including: a transfer device usable in a system for intraluminal treatment of a selected site in a body of a patient (Fig. 2) by a source train of treating elements (Fig. 1a, 19; col. 6, lines 60-62 discloses that the treating elements may also comprise a plurality of radioactive seeds, therefore comprising a source train) advanced through a lumen in the transfer device (Fig. 3, 56) into a lumen of a separate catheter (24), the transfer device

being adapted to receive a source cartridge (30) for storing the source train of treating elements, a system for preventing operation of the transfer device unless each of the catheter and source cartridge are attached thereto, said systems comprising at least one microprocessor (col. 2, lines 13-17); said system for preventing operation of the transfer device (col. 8, lines 6-22) comprising: an illumination source and optical sensor located in the transfer device in proximity to where each of the catheter source cartridge is received by the transfer device, each illumination source being located with respect to its optical sensor so that the optical sensor is able to receive light from its illumination source only if the catheter, fluid cartridge or source cartridge is not received by the transfer device, and the optical sensor being blocked from receiving light from the illumination source when the catheter, fluid cartridge or source cartridge are received by the transfer device (col. 7, line 64 through col. 8, line 5); at least one microprocessor for controlling the movement of the treating element from the transfer device to the catheter (col. 2, lines 13-17), the microprocessor preventing operation of the transfer device upon receiving a signal from any of the optical sensors indicating that at least one of the catheter, fluid cartridge and source cartridge is not attached to the transfer device (col. 8, lines 6-22).

Liprie '008, however, does not specifically disclose that the treating element is advanced through the transfer device by means of pressurized fluid. Waksman, however, discloses that it is common within the art to advance radioactive treating elements through the lumen of a catheter by means of a pressurized fluid (abstract). Therefore it would have been obvious to one of ordinary skill in the art at the time of the

invention to have known to use Liprie '008's device with a pressurized fluid source/cartridge as taught by Waksman (Fig. 1, 14; Fig. 2, 40) in order to move the treating element from the transfer device into a catheter lumen and to the treatment site.

Liprie '008 in view of Waksman, however, do not disclose a graphical interface controlled by the microprocessor. Liprie '333, however, discloses a sensor that senses whether or not the transport tube is attached. If the transport tube is not attached, the operation of the transport device is prevented and an error message with a code number is displayed on the display (col. 8, lines 4-21). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Liprie '008 in view of Waksman with the sensor and display message, as taught by Liprie '333, in order to provide a system that allows the user to understand why the operation of the system is prevented and how to fix the problem.

While Liprie '008 discloses an optical sensor system for determining whether the catheter, fluid cartridge and source cartridge are within the transfer device, Liprie does not disclose a system for determining if one or more of the treating elements are missing from the source cartridge using optical sensors. Meloul, however, discloses a system for determining if one or more of the treating elements is missing from the source cartridge in the transfer device (col. 3, lines 10-24; col. 32, lines 1-10 disclose that the optical system can also be designed to detect two gold marker seeds which therefore when detected indicate that all treating elements between the seeds are in the device, and if the second gold marker seed is not detected, then at least one or more of the treating elements is missing) comprising: a light source including a jacketed fiber

optic bundle disposed on a first side of the storage sleeve to produce a plane of light, a first slot disposed in the first side of the source cartridge, wherein said plane of light is directed towards said first slot; a linear array of photo sensors disposed on second side of the source cartridge, a second slot disposed in the second side of the source cartridge, wherein said photo sensors measure light from the light source that travels through said second slot; at least one microprocessor for comparing the amount of light measured by the photo sensors to a reference amount corresponding to the amount of light measured by the photo sensors when one or more of the treating elements is not within the lumen of the source cartridge, wherein the plane of light shines through the first slot, the storage cartridge and the second slot and is received by the photo sensor when one or more of the treating elements is not within the source cartridge, and wherein if some treating elements are within the source cartridge but one or more of the treating elements is missing from the source cartridge, a portion of the plane of light will shine through the first slot, the source cartridge and the second slot and be received by the photo sensors, the microprocessor then being able to determine based on the amount of light received by the photo sensors that one or more of the treating elements is missing (col. 31, lines 35-67 and col. 32, lines 1-33). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Liprie in view of Waksman and further in view of Liprie, in order to provide a treatment system which allows the user to verify that all treating elements are accounted for, as taught by Meloul, for the purposes of quality assurance as well as for the purpose calculating treatment, so it is not assumed that the correct number of treating elements

were delivered when in fact some were missing, thereby resulting in a less effective treatment.

Claims 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Waksman et al. (US Patent No. 7,160,238) in view of Spako et al. (US Patent no. 5,103,395) and further in view of Meloul et al. (US Patent No. 6,013,020). Waksman discloses the device substantially as claimed including: a transfer device (Fig. 2a) usable in a system for intraluminal treatment of a selected site in a body of a patient by at least one treating element advanced from a translucent Storage sleeve (52) having a lumen into a lumen of a separate catheter (Fig. 1, "catheter") by means of pressurized fluid (abstract). Waksman, however, does not disclose a system for detecting the presence or absence of one or more of the treating elements. Spako, however discloses a system for detecting the presence or absence of the treating element in the translucent storage sleeve comprising; a light source including a jacketed fiber optic bundle disposed on a first side of the storage sleeve to produce a plane of light that intersects at least a portion of the storage sleeve lumen; a linear array of photo sensors disposed on a second side of the storage sleeve so as to measure light from the light source; a microprocessor for' comparing the amount of light measured by the photo sensors to a reference amount corresponding to the amount of light measured by the photo sensors when the treating element is not within the lumen of the storage sleeve (col. 12, lines 67 through col. 13, line 65). Therefore it would have been obvious to one

of ordinary skill in the art at the time of the invention to have modified Waksman's device with the sensors, as taught by Spako, in order to determine whether or not the treating element was in place before treatment. ,

Waksman in view of Spako, however, does not disclose means for detecting whether some of the treatment elements are missing from the storage sleeve. Meloul, however, discloses a way of detecting whether, some, none or all of the treating elements are within the storage sleeve (col. 3, lines 10-24 and col. 31, lines 48-60 and col. 32, lines 1-10 disclose that that the optical system can also be designed to detect two gold marker seeds which therefore when detected indicate that all treating elements between the seeds are in the device, and if the second gold marker seed is not detected, then at least one or more of the treating elements is missing). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Waksman in view of Spako and further in view of Meloul, in order to provide a treatment system which allows the user to verify that all treating elements are accounted for, for the purposes of quality assurance as well as for the purpose calculating treatment, so it is not assumed that the correct number of treating elements were delivered when in fact some were missing, thereby resulting in a less effective treatment.

Response to Arguments

Applicant's arguments filed 10/16/2007 have been fully considered but they are not persuasive. Applicant argues that Meloul only discloses a system for detecting the

presence or absence of a single gold marker seed, however as discussed above, col. 32, lines 1-10 of Meloul disclose another embodiment in which the system is used to detect two gold marker seeds which therefore when detected indicate that all treating elements between the seeds are in the device, and if the second gold marker seed is not detected, then at least one or more of the treating elements is missing. Therefore Waksman in view of Spako and further in view of Meloul still anticipate claims 20-22.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER



